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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/370,860 08/09/99 KADURUGAMUWA

J 7933.36US01

HM12/0421

EXAMINER

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ART UNIT	PAPER NUMBER
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1645

DATE MAILED:

04/21/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

**Office Action Summary**Application No.  
**09/370,860**

Applicant(s)

**Kadurugamuwa et al.**

Examiner

**Robert A. Zeman**

Group Art Unit

**1645** Responsive to communication(s) filed on Aug 9, 1999. This action is **FINAL**. Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 1 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

**Disposition of Claims** Claim(s) 1-17 is/are pending in the application.

Of the above, claim(s) \_\_\_\_\_ is/are withdrawn from consideration.

 Claim(s) \_\_\_\_\_ is/are allowed. Claim(s) \_\_\_\_\_ is/are rejected. Claim(s) \_\_\_\_\_ is/are objected to. Claims 1-17 are subject to restriction or election requirement.**Application Papers** See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948. The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner. The proposed drawing correction, filed on \_\_\_\_\_ is  approved  disapproved. The specification is objected to by the Examiner. The oath or declaration is objected to by the Examiner.**Priority under 35 U.S.C. § 119** Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d). All  Some\*  None of the CERTIFIED copies of the priority documents have been received. received in Application No. (Series Code/Serial Number) \_\_\_\_\_. received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\*Certified copies not received: \_\_\_\_\_.

 Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).**Attachment(s)** Notice of References Cited, PTO-892 Information Disclosure Statement(s), PTO-1449, Paper No(s). \_\_\_\_\_ Interview Summary, PTO-413 Notice of Draftsperson's Patent Drawing Review, PTO-948 Notice of Informal Patent Application, PTO-152**--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---**

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## **DETAILED ACTION**

### ***Election/Restriction***

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-6, drawn to vaccines, classified in class 424, subclass 234.1.
- II. Claims 7-12, drawn to pharmaceutical compositions and method of treating infectious diseases, classified in class 424, subclass 94.1.
- III. Claims 13 and 14, drawn to drug delivery systems, classified in class 424, subclass 400.
- IV. Claims 15-17, drawn to methods of inserting DNA into a cell , classified in class 435, subclass 440.

The inventions are distinct, each from the other because of the following reasons:

Inventions I and II are separate and distinct as they comprise completely differing biochemical and immunological entities having differing properties and uses. In the instant case the claims of Invention I are drawn to vaccines whereas Invention II is drawn to pharmaceutical compositions.

Inventions I and III are separate and distinct as they comprise completely differing biochemical and immunological entities having differing properties and uses. In the instant case the claims of Invention I are drawn to vaccines whereas Invention III is drawn to drug delivery systems.

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Inventions I and IV are separate and distinct as the vaccines of Invention I cannot be used in the methods of Invention IV.

Inventions II and III are separate and distinct as they comprise completely differing biochemical and immunological entities having differing properties and uses. In the instant case the claims of Invention II are drawn to pharmaceutical compositions whereas Invention III is drawn to drug delivery systems.

Inventions II and IV are separate and distinct as the vaccines of Invention II cannot be used in the methods of Invention IV.

Inventions III and IV are separate and distinct as the drug delivery systems of Invention III cannot be used in the methods of Invention IV.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification and because the search for each group is not coextensive with search for any other group, restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently

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named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(I).

Claim 3 is generic to a plurality of disclosed patentably distinct species comprising *Pseudomonas aeruginosa*, *Escherichia coli*, *Salmonella gastroenteritis (typhimurium)*, *S. typhi*, *S. enteriditidis*, *Shigella flexneri*, *S. sonnie*, *S. dysenteriae*, *Neisseria gonorrhoeae*, *N. meningitidis*, *Haemophilus influenzae*, *H. pleuropneumoniae*, *Pasteurella haemolytica*, *P. multilocida*, *Legionella pneumophila*, *Treponema pallidum*, *T. denticola*, *T. oralis*, *Borrelia brugdorferi*, *Borrelia spp.*, *Leptospira interrogans*, *Klebsiella pneumoniae*, *Proteus vulgaris*, *P. morganii*, *P. mirabilis*, *Rickettsia prowazekii*, *R. typhi*, *R. rickettsii*, *Porphyomonas (Bacteroides) gingivalis*, *Chlamydia psittaci*, *C. pneumoniae*, *C. trachomatis*, *Campylobacter jejuni*, *C. intermedius*, *C. fetus*, *Helicobacter pylori*, *Francisella tularensis*, *Vibrio cholerae*, *Vibrio parahaemolyticus*, *Bordetella pertussis*, *Burkholderia pseudomallei*, *Brucella abortus*, *B. suis*, *B. melitensis*, *B. canis*, *Spirillum minus*, *Pseudomonas mallei*, *Aeromonas hydrophila*, *A. salmonicida* or *Yersinia pestis*. Applicant is required under 35 U.S.C. 121 to elect a single disclosed species, even though this requirement is traversed.

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the

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examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert A. Zeman whose telephone number is (703) 308-7991. The examiner can be reached between the hours of 7:30 am and 4:00 pm Monday through Friday.

If attempts to reach the examiner by telephone are unsuccessful, Donna Wortman, Primary Examiner can be reached at (703) 308-1032.

The fax number for this Art Unit is (703) 305-7401.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

  
DONNA WORTMAN  
PRIMARY EXAMINER

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Robert A. Zeman

April 13, 2000